Food and Drug Administration, HHS

- (c) Conditions of use in dogs—(1) Amount. Instill five drops in the ear canal twice daily for 7 consecutive days.
- (2) Indications for use. For the treatment of canine otitis externa associated with susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius).
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 4693, Jan. 29, 2010]

§ 524.1446 Milbemycin oxime solution.

- (a) *Specifications*. Each tube contains 0.25 milliliter of a 0.1 percent solution of milbernycin oxime.
- (b) Sponsor. See No. 058198 in \$510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. One tube administered topically into each external ear canal.
- (2) Indications for use. For the treatment of ear mite (Otodectes cynotis) infestations in cats and kittens 4 weeks of age and older. Effectiveness is maintained throughout the life cycle of the ear mite.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[65 FR 13905, Mar. 15, 2000, as amended at 66 FR 13849, Mar. 8, 2001]

§ 524.1451 Moxidectin.

- (a) Specifications. Each milliliter contains 5 milligrams of moxidectin (0.5 percent solution).
- (b) Sponsor. See No. 000856 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.426 of this chapter.
- (d) Special considerations. See §500.25 of this chapter.
- (e) Conditions of use-(1) Amount. 0.5 milligrams moxidectin per kilogram (2.2 pounds) of body weight.
- (2) Indications for use. Beef and dairy cattle: For treatment and control of internal and external parasites: gastro-intestinal roundworms (Ostertagia ostertagi (adult and L4, including inhibited larvae), Haemonchus placei (adult and L4), Trichostrongylus axei (adult and L4), T. colubriformis (adult and L4), Coperia oncophora (adult and L4), C. pectinata (adult), C. punctata (adult and

- L4), C. spatulata (adult), C. surnabada (adult and L4), Bunostomum phlebotomum (adult), Oesophagostomum radiatum (adult and L4), Nematodirus helvetianus (adult and L4)): lungworms (Dictyocaulus viviparus, adult and L4); cattle grubs (Hypoderma bovis, H. lineatum); mites (Chorioptes bovis, Psoroptes ovis (P. communis var. bovis)); lice (Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus. Bovicola(Damalinia) bovis); and horn flies (Haematobia irritans). To control infections and to protect from reinfection with H. placei for 14 days after treatment, O. radiatum and O. ostertagi for 28 days after treatment, and D. viviparus for 42 days after treatment.
- (3) *Limitations*. A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for yeal.
- [63 FR 14036, Mar. 24, 1998, as amended at 65 FR 36617, June 9, 2000; 66 FR 46370, Sept. 5, 2001]

§ 524.1465 Mupirocin.

- (a) Specifications. Each gram of ointment contains 20 milligrams mupirocin.
- (b) *Sponsors*. See Nos. 000069, 025463, and 051672 in §510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Apply twice daily. Treatment should not exceed 30 days.
- (2) Indications for use. For the topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of Staphylococcus aureus and S. intermedius.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 18119, Apr. 11, 2007, as amended at 75 FR 79296, Dec. 20, 2010]

§ 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

§ 524.1484a Neomycin sulfate oph thalmic ointment.

- (a) *Specifications*. Each gram of the ointment contains 5 milligrams of neomycin sulfate equivalent in activity to 3.5 milligrams of neomycin base.
- (b) *Sponsor*. See No. 017030 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) The drug is intended for use in dogs and cats for